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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,415

01/23/2004

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20999 7590 04/16/2008  
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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/764,415	BODMER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SANDRA WEGERT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 10-13, 15-17, 24, 25, 29-33, 35-45 and 48-84 is/are pending in the application.
- 4a) Of the above claim(s) 15-17, 24, 25 and 50-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 13, 29, 30, 35-45, 48, 49, 83 and 84 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

#### ***Status of Application, Amendments, and/or Claims***

The Remarks and Amendment, received 11 January 2008, have been entered. The Information Disclosure Statement, received 27 February 2008, has been considered. Claims 1, 10, 11, 13, 29, 30, 32, 33, 35, 36, 37, 40, 41, 42, 45, 49, 83 and 84 have been amended. Claims 2-9, 14, 18-23, 26-28, 34, 46 and 47 have been cancelled. Claims 1, 10-13, 29-33, 35-45, 48, 49, 83 and 84 are under examination.

#### **Withdrawn Objections and/or Rejections**

##### ***Specification***

The objection to the disclosure, for containing an embedded hyperlink, is *withdrawn*. Applicants amended the Specification to remove the URL on page 33 (11 January 2008).

The objection to the Brief Description for not being fully descriptive when referencing the figures is *withdrawn*. Applicants amended the Specification to insert detailed captions concerning the content of the figures (11 January 2008).

The objection to the Brief Description for referring to the two views of Figure 30 as "A" and "B" is *withdrawn*. Applicants amended the Brief Description to refer to the two views as "Expt 1" and "Expt 2," as shown in the figures (11 January 2008).

***Claim Objections-***

The objection to Claim 37 for missing a period at the end of line 2, is *withdrawn*. Applicants amended the claim to add a period (11 January 2008).

Similarly, the objection to Claim 42 for missing a period at the end of line 1, is *withdrawn*. Applicants amended the claim to add a period (11 January 2008).

The objection to Claim 45 for recitation of "and" inappropriately, is *withdrawn*. Applicants amended the claim to remove the first recitation of the word "and" (11 January 2008).

The objection to claim 19, for using acronyms that have not been defined in the claims, is *withdrawn*. Applicants have cancelled Claim 19 (11 January 2008).

The objection to Claims 37-38 for using the acronym "TCR" without first defining what it represents in the independent claims, is *withdrawn*. Applicants amended independent claim 37 to recite "anti-T-cell receptor" (11 January 2008).

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

The rejection of claims 83 and 84 for not referring to the method by which molecular weight was calculated, is *withdrawn*. This rejection was made in the previous Office Action (12 July 2007, p. 4). Applicants amended the independent claim to recite use of "SDS-PAGE" (11 January 2008).

***Claim Rejections- 35 U.S.C. § 112, first paragraph- Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

The rejection of Claims 1-14, 18-23, 26-49, and 83-84 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, is *withdrawn*, based on applicants' arguments and on the claim amendments submitted 11 January 2008. Applicants cancelled claims 2-9, 18-23, 26-28, 34 and 46-47. Remaining claims were amended to recite use of specific products that applicants were in possession of for the claimed methods, such as: T-cells and the specific cytokines IL-5, IL-10, IL-13 and IFN gamma (11 January 2008).

The rejection of claims 1-14, 18-23, 26-49, and 83-84, under 35 U.S.C. § 112, first paragraph, for improper Scope of Enablement, is *withdrawn*, based on claim amendments and applicant's arguments (27 February 2008). Claims 2-9, 14, 18-23, 26-28, 34 and 46-47 have been cancelled by applicants. Remaining independent claims have been amended to recite

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specific method steps enabled by the specification, such as 1) activation of T-cells, 2) contacting T-cells with a candidate modulator, and, 3) monitoring the levels of cytokines produced by the activated T-cells. Applicants also argued effectively that the claims are enabled for a variety of Notch ligands, as disclosed in the Specification at pages 17 and 18 (11 January 2008).

**Maintained/New Objections and/or Rejections**

***Claim Objections-***

Claims 10, 11, 13, 29, 30, 35-45, 48, 49, 83 and 84 are objected to for depending from a rejected base claim.

***Claim Rejections - 35 USC § 112, second paragraph***

The rejection of claims 32 and 33 for not referring to the method by which molecular weight was calculated, is *maintained*. This rejection was made in the previous Office Action (12 July 2007, p. 4) because applicants did not include the method in the claims by which molecular weight was determined. Applicants amended the claims to insert the unit of measurement (Daltons), but did not insert the method used (such as "SDS-PAGE").

***Claim Rejections - 35 USC § 102.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

The rejection of claims 1, 12 and 31 under 35 U.S.C. § 102(b) for being anticipated by Gehring et al. (WO 200103743; published on 18 January 2001), is *maintained*. This rejection was previously made over claims 1, 2, 4, 5, 7-9, and 31 (12 July 2007, pp. 13 and 14). Applicants have cancelled claims 2, 4, 5 and 7-9 (11 January 2008).

Gehring et al teach a method of screening for agonists and antagonists of Notch pathway function comprising: 1) contacting the cell with an agonist or antagonist of the cell fate control function and concurrently treating the cell with a test agonist or antagonist of the Notch pathway function; 2) subjecting the cell to conditions that allow cell fate determination to occur; and, 3) examining the cell for an alteration of cell fate (page 51, lines 19-24). Thus, the teachings of Gehring, et al meet the limitations of claims 1, 12 and 31 of the instant application. Gehring *et al* disclose that experimental cells can be primary cells or cell lines from any species (page 52, lines 10-13). Gehring et al. also teach that Notch pathway agonists and antagonists include nucleic acids, antibodies, peptidomimetics or peptide analog, or organic molecules (page 38, line 36 through page 39, lines 1-5; page 43, lines 14-19; page 44, especially lines 24-35).

Applicants argue that the reference does not teach use of T-cells or measurement of cytokines in the Gehring et al cell-fate experiments (Remarks, 11 January 2008, p. 17). However, the reference contemplates use of primary cells or cell lines from any species (p. 52), including T-cells specifically (p. 9, last paragraph) for studying Notch, as well as cytokine proliferation signals as they relate generally to Notch signaling (p. 12, bottom of the page and p. 13, under "Signaling Molecules").

***Conclusion***

Claims 1, 12, 31-33, are rejected. Claims 10, 11, 13, 29, 30, 35-45, 48, 49, 83 and 84 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

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If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/Marianne P. Allen/

Primary Examiner, Art Unit 1647

/SLW/

8 April 2008